

Remarks

Applicant's representative would again like to thank Examiner Lucas and his supervisor Examiner Housel for the very useful interview of December 11, 2003. The present amendments and following remarks are made pursuant to the issues discussed at the interview.

Objections to the claims

Claim 2 had been objected to as being improper for the recitation of contacting with a lipoheptapeptide at "higher than room temperature" because claim 1 previously limits the temperature to room temperature. Claim 2 has been amended to be in independent form. Support for the amendment to claim 2 may be found on page 5, final paragraph.

Rejections under 35 U.S.C. §112, 2nd paragraph

Claims 1-11 and 13-15 have been rejected as being unclear in the recitation of "by a factor of approximately $>10^4$ " for two reasons.

a) The Examiner asserts that "approximately $>10^4$ " is confusing because it is unclear what is meant by being approximately greater than a number.

b) The Examiner further asserts that the claims need to recite a viral titer of at least 10^4 because if the viral titer was lower than 10^4 , the composition would have a negative viral titer.

Claim 1 has been amended as was suggested by the Examiners during the interview. During the interview it was noted that certain terms were superfluous to the claims and that the invention would be most clearly defined by the end achieved with the invention, i.e. "in an amount and for a time and at a temperature effective to inactivate substantially all lipid-enveloped viruses in the composition." Withdrawal of the rejection is therefore respectfully requested.

Rejections under 35 U.S.C. §103

Claims 1, 3-7, 9, 10, 14, 15, and 18 have been rejected as being obvious over Itokawa et al., Chem. Pharm. Bull. 42(3):604-607, newly combined with Budowsky et al. (U.S. Pat. No. 6,114,108). Itokawa et al. is asserted to teach that surfactins from *B. subtilis* have antiviral activity. Itokawa et al. is also asserted to teach a surfactin concentration within the claimed range. Itokawa et al. is asserted to differ from the invention in failing to teach the use of surfactins to render a composition of an isolated product substantially virus free. Budowsky is asserted to teach the use of anti-viral compounds to inactivate

viruses in a composition such as blood. Applicants traverse this rejection and withdrawal thereof is respectfully requested.

As discussed during the interview, the only disclosure in Itokawa et al. regarding HIV activity was the brief statement that moderate anti-HIV activity was observed in the XTT assay. The Weislow et al. article, which was reviewed with the Examiners during the interview, discusses the XTT assay used in Itokawa et al. When Itokawa et al. is read in view of Weislow et al., only moderate anti-viral activity was achieved after exposure to the lipopeptides for 7 days at 37°C. Based on these findings, one skilled in the art would not expect to be able to achieve effectively 100% viral inactivation after only 2 hours at room temperature. In addition, the cellular assays of Itokawa et al. are not indicative of direct viral inactivation, as achieved with the invention. As such, the present invention is not obvious over the Itokawa combined with Budowsky.

Claims 2 and 13 have been rejected as being obvious over Itokawa combined with Naruse and Horowitz. The Examiner further rejects claims 8 and 11 over Itokawa et al., Naruse et al. and Vater et al. combined with Budowsky et al. The additional references of Naruse, Horowitz and Vater further fail to suggest that effectively 100% inactivation after only at most 2 hours could be achieved with the surfactins of the invention. As such,

the invention is not achieved or suggested when Itokawa and Budowsky are further combined with Naruse, Horowitz and/or Vater. The invention of claims 2, 8, 11 and 13 is therefore not obvious over the cited references and withdrawal of the rejection is respectfully requested.

If any questions remain regarding the above matters, please contact Applicant's representative, MaryAnne Armstrong, PhD (Reg. No. 40,069), in the Washington metropolitan area at the phone number listed below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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